

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2008 has been entered.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "reference standard" is not disclosed or suggested by the specification as originally filed.

Applicant's arguments filed March 3, 2008 have been fully considered but they are not persuasive.

Applicant has failed to point out where in the specification, as originally filed, support can be found for the use of a reference standard as encompassed by claim 11.

Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 11, 2006.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bright (U.S. Patent No. 4,474,768).

Bright discloses a pharmaceutical composition comprising azithromycin (column 7, lines 23-54). The claimed degradation product is inherently contained in said composition since the specification on page 2, lines 16-17 states that azithromycin degrades during manufacture and/or storage.

Applicant's arguments filed March 3, 2008 have been fully considered but they are not persuasive.

Applicant contends that azithromycin may be stored in a variety of conditions that will determine whether or not degradation occurs and if so what degradation products occur. This argument has not been found persuasive since the present specification teaches that azithromycin degrades producing the claimed compound i.e. the specification does not teach that the claimed compound is produced under any special conditions. Further, applicant has not provided any evidence that the claimed product is not inherently contained in the composition disclosed by Bright.

Claims 3 and 11 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Centellas et al (U.S. Patent No. 6,949,519) or Tenengauzer et al (U.S. Patent No. 6,764,997).

Centellas et al disclose that azithromycin compositions contain degradation products and further disclose the percentage of azithromycin degradation product present (column 1, lines 53-67 and column 2, lines 1-18).

Tenengauzer et al disclose that azithromycin degrades when exposed to temperatures above about 25 C (column 2, lines 63-67) and further disclose a method of determining the amount of a degradation product present in Example 2, columns 9-11.

The claimed degradation product is inherently contained in the compositions disclosed by Centellas et al or Tenengauzer et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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